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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/028,400

12/20/2001

Diana Zanini

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3607

27777 7590 04/01/2009  
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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/028,400	<b>Applicant(s)</b> ZANINI ET AL.	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,14-17,19,21-24 and 73-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,14-17,19,21-24 and 73-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20090113,20081215</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/13/2009 has been entered.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-11, 14-17, 19, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP55-38855 in view of Gibbins et al. (US Pat. 6,605,751), the acknowledged prior art, Vanderlaan et al. (US Pat. 5,998,498), Laskey (US Pat. 3,929,741), Nochumson (US Pat. 4,542,200), Malecki et al. and Tilley.

JP55-38855 disclose that 2-acryl amide-2-methyl propane sulfonic acid binds with antimicrobial metal, such as silver, which when formulated into films, including porous films, provides a time-releasable antimicrobial material having long-term effectiveness. It is disclosed that monomers copolymerizable with the binding monomer can be selected from a wide range according to the application of the producing antimicrobial material, and include ethylene, propylene, vinyl chloride, vinylidene chloride, vinyl acetic acid, acrylic acid ester, methacrylic acid ester, styrene, butadiene, acryl amide, aryl compound. It is disclosed that the antimicrobial

metallic ions can be introduced by bringing the product in contact with said metal ions, for example soaking the product in an aqueous solution of silver nitrate for 20 minutes (See entire English translation of JP 55-38855, especially Pgs. 2-6, 9-13 thereof).

Gibbins et al. disclose the use of silver as an antimicrobial in contact lenses (Column 8, lines 58-67).

The Applicant acknowledges that soft contact lenses based on hydrogels are widely used because they are more comfortable but that extended use encourages the build of bacteria and other microbes (Pg. 1). It is acknowledged that examples of these soft contact lens, include etafilcon A, balafilcon A, aquafilcon A, lenefilcon, lotrafilcon and silicone hydrogels (Pg. 20, lines 1-8).

Vanderlaan et al. teach that soft contacts can be prepared from silicone hydrogels which combine silicone containing monomers and hydrophilic monomers (See entire reference, especially column 5).

Laskey teaches that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties (Column 1).

Nochumson discloses that N,N'-bisacrylylcystamine is used as a cross-linker in producing polyacrylamide gels (Column 1, lines 55-61).

Malecki et al. disclose methods of determining stability constants of silver with various ligands and that antibacterial activity is related to solubility (Abstract).

Tilley disclose determination of stability constants of various complexes with silver (Abstract).

JP55-38855 discloses the complexes of silver with ligands and contact lenses containing the same. The difference between JP55-38855 and the claimed invention is that the prior art does not expressly disclose an antimicrobial contact lens comprising silver and a polymer

comprising a monomer of formula  $\left( \text{CH}_2 = \text{CH} - \text{C}(=\text{O}) - \text{NH} - \text{CH}_2 - \text{CH}_2 - \text{S} - \right)_2$ . However, the prior art amply suggests the same as Gibbons discloses the combination of contact lenses and silver; the Applicant acknowledges that hydrogel contact lenses are subject to bacterial contamination; Laskey discloses that hydrophilic monomers of acrylamido sulfonic acid or sulfonate are suitable for soft contact lenses and have greater water retention and because of a greater ability for cross-linking have increased flexibility in the modification of physical properties; Nochumson discloses that N,N'-bisacrylylcystamine is used as a cross-linker in producing polyacrylamide gels; Malecki et al. disclose methods of determining stability constants of silver with various ligands and that antibacterial activity is related to solubility; and Tilley disclose determination of stability constants of various complexes with silver. As such, it would have been well within the skill of one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the soft contact lenses produced would have antimicrobial properties and be time-releasable while having long-term effectiveness and, thus, avoid the problems associated with extended wear. Further, it would have been well within the skill of one of ordinary skill in the art to determine the stability constant of a given silver complex with the binding monomer with the expectation that the relative antimicrobial activity could be predicted. Furthermore, it would have been well within the skill of one of ordinary skill in the art to prepare the antimicrobial lens by soaking the lens containing the binding monomer in an aqueous solution containing the silver ions with the expectation that the silver ions would bind with the binding

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monomers contained in the contact lens. Finally, one of ordinary skill in the art would have expected that N,N'-bisacrylylcystamine would have been suitable as a cross-linker in contact lenses containing polyacrylamide and that cross-linking would provide greater water retention and flexibility in the contact lens.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,4-11,14-17, 19, 21-24, 73-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22,24-27 of copending Application No. 10/734,762. Although the conflicting claims are not identical, they

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are not patentably distinct from each other because the copending applications disclose a method of preparing antimicrobial contact lenses wherein the antimicrobial contact lenses contain the same monomers and antimicrobial silver, and preparation of the contact lens by soaking the contact lens containing said monomers in an aqueous silver solution, such as a silver nitrate for a period of at least 20 minutes, as that claimed in the present application.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive. Since the application is not yet allowable, the Examiner will not withdraw the provisional double patenting rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
April 1, 2009

/Johann R. Richter/

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